

APPLICATION FOR U.S. PATENT

METHOD AND APPARATUS FOR PERFORMING CATHETER-BASED
ANNULOPLASTY USING LOCAL PLICATIONS

INVENTORS: Edwin J. Hlavka
2246 Harvard Street
Palo Alto, California 94306
A Citizen of the United States of America

Jonathan L. Podmore
444 15th Avenue Apt. 307
San Francisco, California 94118-2842
A Citizen of the United States of America

Paul A. Spence
5818 Orion Road
Louisville, Kentucky 40222
A Citizen of Canada

RITTER LANG & KAPLAN LLP
12930 Saratoga Avenue, Suite D1
Saratoga, California 95070
Telephone (408) 446-8690

METHOD AND APPARATUS FOR CATHETER-BASED ANNULOPLASTY USING LOCAL PLICATIONS

CROSS REFERENCE TO RELATED APPLICATION

The present invention is a Continuation-in-Part of co-pending U.S. Patent
5 Application No. 09/841,968, entitled "Method and Apparatus for Catheter-Based
Annuloplasty," filed April 24, 2001, which is incorporated herein by reference in its
entirety.

BACKGROUND OF THE INVENTION

1. Field of Invention

10 The present invention relates generally to techniques for treating mitral valve
insufficiencies such as mitral valve leakage. More particularly, the present invention
relates to systems and methods for treating a leaking mitral valve in a minimally invasive
manner.

2. Description of the Related Art

15 Congestive heart failure (CHF), which is often associated with an enlargement of
the heart, is a leading cause of death. As a result, the market for the treatment of CHF is
becoming increasingly prevalent. For instance, the treatment of CHF is a leading
expenditure of Medicare and Medicaid dollars in the United States of America.
Typically, the treatment of CHF enables many who suffer from CHF to enjoy an
20 improved quality of life.

Referring initially to Fig. 1, the anatomy of a heart, specifically the left side of a
heart, will be described. The left side of a heart 104 includes a left atrium 108 and a left
ventricle 112. An aorta 114 receives blood from left ventricle 112 through an aortic
valve 120, which serves to prevent regurgitation of blood back into left ventricle 112. A
25 mitral valve 116 is disposed between left atrium 108 and left ventricle 112, and
effectively controls the flow of blood between left atrium 108 and left ventricle 112.

Mitral valve 116, which will be described below in more detail with respect to Fig. 2a, includes an anterior leaflet and a posterior leaflet that are coupled to cordae tendonae 124 which serve as "tension members" that prevent the leaflets of mitral valve 116 from opening indiscriminately. When left ventricle 112 contracts, cordae tendonae 124 allow the anterior leaflet to open upwards until limited in motion by cordae tendonae 124. Normally, the upward limit of opening corresponds to a meeting of the anterior and posterior leaflets and the prevention of backflow. Cordae tendonae 124 arise from a columnae carnae 128 or, more specifically, a muscoli papillares of columnae carnae 128.

Left ventricle 112 includes trabeculae 132 which are fibrous cords of connective tissue that are attached to wall 134 of left ventricle 112. Trabeculae 132 are also attached to an interventricular septum 136 which separates left ventricle 112 from a right ventricle (not shown) of heart 104. Trabeculae 132 are generally located in left ventricle 112 below columnae carnae 128.

Fig. 2a is a cut-away top-view representation of mitral valve 116 and aortic valve 120. Aortic valve 120 has a valve wall 204 that is surrounded by a skeleton 208a of fibrous material. Skeleton 208a may generally be considered to be a fibrous structure that effectively forms a ring around aortic valve 120. A fibrous ring 208b, which is substantially the same type of structure as skeleton 208a, extends around mitral valve 116. Mitral valve 116 includes an anterior leaflet 212 and a posterior leaflet 216, as discussed above. Anterior leaflet 212 and posterior leaflet 216 are generally thin, flexible membranes. When mitral valve 116 is closed (as shown in Fig. 2a), anterior leaflet 212 and posterior leaflet 216 are generally aligned and contact one another to create a seal. Alternatively, when mitral valve 116 is opened, blood may flow through an opening created between anterior leaflet 212 and posterior leaflet 216.

Many problems relating to mitral valve 116 may occur and these insufficiencies may cause many types of ailments. Such problems include, but are not limited to, mitral regurgitation. Mitral regurgitation, or leakage, is the backflow of blood from left ventricle 112 into the left atrium 108 due to an imperfect closure of mitral valve 116. That is, leakage often occurs when a gap is created between anterior leaflet 212 and posterior leaflet 216.

In general, a relatively significant gap may exist between anterior leaflet 212 and posterior leaflet 216 (as shown in Fig. 2b) for a variety of different reasons. For example, a gap may exist due to congenital malformations, because of ischemic disease, or because a heart has been damaged by a previous heart attack. A gap may also be created when congestive heart failure, *e.g.*, cardiomyopathy, or some other type of distress causes a heart to be enlarged. When a heart is enlarged, the walls of the heart, *e.g.*, wall 134 of a left ventricle, may stretch or dilate, causing posterior leaflet 216 to stretch. It should be appreciated that anterior leaflet 212 generally does not stretch. As shown in Fig. 2b, a gap 220 between anterior leaflet 212 and stretched posterior leaflet 216' is created when wall 134' stretches. Hence, due to the existence of gap 220, mitral valve 116 is unable to close properly, and may begin to leak.

Leakage through mitral valve 116 generally causes a heart to operate less efficiently, as the heart must work harder to maintain a proper amount of blood flow therethrough. Leakage through mitral valve 116, or general mitral insufficiency, is often considered to be a precursor to CHF. There are generally different levels of symptoms associated with heart failure. Such levels are classified by the New York Heart Association (NYHA) functional classification system. The levels range from a Class 1 level which is associated with an asymptomatic patient who has substantially no physical limitations to a Class 4 level which is associated with a patient who is unable to carry out any physical activity without discomfort, and has symptoms of cardiac insufficiency even at rest. In general, correcting for mitral valve leakage may be successful in allowing the NYHA classification grade of a patient to be reduced. For instance, a patient with a Class 4 classification may have his classification reduced to Class 3 and, hence, be relatively comfortable at rest.

Treatments used to correct for mitral valve leakage or, more generally, CHF, are typically highly invasive, open-heart surgical procedures. Ventricular assist devices such as artificial hearts may be implanted in a patient whose own heart is failing. The implantation of a ventricular assist device is often expensive, and a patient with a ventricular assist device must be placed on extended anti-coagulant therapy. As will be appreciated by those skilled in the art, anti-coagulant therapy reduces the risk of blood

clots being formed, as for example, within the ventricular assist device. While reducing the risks of blood clots associated with the ventricular assist device is desirable, anti-coagulant therapies may increase the risk of uncontrollable bleeding in a patient, *e.g.*, as a result of a fall, which is not desirable.

5 Rather than implanting a ventricular assist device, bi-ventricular pacing devices similar to pace makers may be implanted in some cases, *e.g.*, cases in which a heart beats inefficiently in a particular asynchronous manner. While the implantation of a bi-ventricular pacing device may be effective, not all heart patients are suitable for receiving a bi-ventricular pacing device. Further, the implantation of a bi-ventricular pacing device
10 is expensive.

Open-heart surgical procedures which are intended to correct for mitral valve leakage, specifically, involve the implantation of replacement valves. Valves from animals, *e.g.*, pigs, may be used to replace a mitral valve 116 in a human. While the use of a pig valve may relatively successfully replace a mitral valve, such valves generally
15 wear out, thereby requiring additional open surgery at a later date. Mechanical valves, which are less likely to wear out, may also be used to replace a leaking mitral valve. However, when a mechanical valve is implanted, there is an increased risk of thromboembolism, and a patient is generally required to undergo extended anti-coagulant therapies.

20 A less invasive surgical procedure involves heart bypass surgery associated with a port access procedure. For a port access procedure, the heart may be accessed by cutting a few ribs, as opposed to opening the entire chest of a patient. In other words, a few ribs may be cut in a port access procedure, rather than opening a patient's sternum.

One open-heart surgical procedure that is particularly successful in correcting for
25 mitral valve leakage and, in addition, mitral regurgitation, is an annuloplasty procedure. During an annuloplasty procedure, an annuloplasty ring may be implanted on the mitral valve to cause the size of a stretched mitral valve 116 to be reduced to a relatively normal size. Fig. 3 is a schematic representation of an annuloplasty ring. An annuloplasty ring
304 is shaped approximately like the contour of a normal mitral valve. That is,
30 annuloplasty ring 304 is shaped substantially like the letter "D." Typically, annuloplasty

ring 304 may be formed from a rod or tube of biocompatible material, *e.g.*, plastic, that has a DACRON mesh covering.

In order for annuloplasty ring 304 to be implanted, a surgeon surgically attaches annuloplasty ring 304 to the mitral valve on the atrial side of the mitral valve.

5 Conventional methods for installing ring 304 require open-heart surgery which involve opening a patient's sternum and placing the patient on a heart bypass machine. As shown in Fig. 4, annuloplasty ring 304 is sewn to a posterior leaflet 318 and an anterior leaflet 320 of a top portion of mitral valve 316. In sewing annuloplasty ring 304 onto mitral valve 316, a surgeon generally alternately acquires a relatively large amount of tissue
10 from mitral tissue, *e.g.*, a one-eighth inch bite of tissue, using a needle and thread, followed by a smaller bite from annuloplasty ring 304. Once a thread has loosely coupled annuloplasty ring 304 to mitral valve tissue, annuloplasty ring 304 is slid onto mitral valve 316 such that tissue that was previously stretched out, *e.g.*, due to an enlarged heart, is effectively pulled in using tension applied by annuloplasty ring 304 and
15 the thread which binds annuloplasty ring 304 to the mitral valve tissue. As a result, a gap, such as gap 220 of Fig. 2b, between anterior leaflet 320 and posterior leaflet 318 may be substantially closed off. After the mitral valve is shaped by ring 304, the anterior and posterior leaflets 320, 318 will reform to create a new contact line and will enable mitral valve 318 to appear and to function as a normal mitral valve.

20 Once implanted, tissue generally grows over annuloplasty ring 304, and a line of contact between annuloplasty ring 304 and mitral valve 316 will essentially enable mitral valve 316 to appear and function as a normal mitral valve. Although a patient who receives annuloplasty ring 304 may be subjected to anti-coagulant therapies, the therapies are not extensive, as a patient is only subjected to the therapies for a matter of weeks,
25 *e.g.*, until tissue grows over annuloplasty ring 304.

A second surgical procedure which is generally effective in reducing mitral valve leakage involves placing a single edge-to-edge suture in the mitral valve. With reference to Fig. 5a, such a surgical procedure, *e.g.*, an Alfieri stitch procedure or a bow-tie repair procedure, will be described. An edge-to-edge stitch 404 is used to stitch together an
30 area at approximately the center of a gap 408 defined between an anterior leaflet 420 and

a posterior leaflet 418 of a mitral valve 416. Once stitch 404 is in place, stitch 404 is pulled in to form a suture which holds anterior leaflet 420 against posterior leaflet 418, as shown. By reducing the size of gap 408, the amount of leakage through mitral valve 416 may be substantially reduced.

5 Although the placement of edge-to-edge stitch 404 is generally successful in reducing the amount of mitral valve leakage through gap 408, edge-to-edge stitch 404 is conventionally made through open-heart surgery. In addition, the use of edge-to-edge stitch 404 is generally not suitable for a patient with an enlarged, dilated heart, as blood pressure causes the heart to dilate outward, and may put a relatively large amount of
10 stress on edge-to-edge stitch 404. For instance, blood pressure of approximately 120/80 or higher is typically sufficient to cause the heart to dilate outward to the extent that edge-to-edge stitch 404 may become undone, or tear mitral valve tissue.

 Another surgical procedure which reduces mitral valve leakage involves placing sutures along a mitral valve annulus around the posterior leaflet. A surgical procedure
15 which places sutures along a mitral valve will be described with respect to Fig. 5b. Sutures 504 are formed along an annulus 540 of a mitral valve 516 around a posterior leaflet 518 of mitral valve 516, and may be formed as a double track, *e.g.*, in two "rows," from a single strand of suture material. Sutures 504 are tied off at approximately a
20 central point 506 of posterior leaflet 518. Pledgets 546 are often positioned under selected sutures 504, *e.g.*, at central point 506, to prevent sutures 504 from tearing through annulus 540. When sutures 504 are tied off, annulus 540 may effectively be
tightened to a desired size such that the size of a gap 508 between posterior leaflet 518 and an anterior leaflet 520 may be reduced.

 The placement of sutures 504 along annulus 540, in addition to the tightening of
25 sutures 504, is generally successful in reducing mitral valve leakage. However, the placement of sutures 504 is conventionally accomplished through open-heart surgical procedures. That is, like other conventional procedures, a suture-based annuloplasty procedure is invasive.

 While invasive surgical procedures have proven to be effective in the treatment of
30 mitral valve leakage, invasive surgical procedures often have significant drawbacks. Any

time a patient undergoes open-heart surgery, there is a risk of infection. Opening the sternum and using a cardiopulmonary bypass machine has also been shown to result in a significant incidence of both short and long term neurological deficits. Further, given the complexity of open-heart surgery, and the significant associated recovery time, people who are not greatly inconvenienced by CHF symptoms, *e.g.*, people at a Class 1 classification, may choose not to have corrective surgery. In addition, people who most need open heart surgery, *e.g.*, people at a Class 4 classification, may either be too frail or too weak to undergo the surgery. Hence, many people who may benefit from a surgically repaired mitral valve may not undergo surgery.

Therefore, what is needed is a minimally invasive treatment for mitral valve leakage. Specifically, what is desired is a method for reducing leakage between an anterior leaflet and a posterior leaflet of a mitral valve that does not require conventional surgical intervention.

SUMMARY OF THE INVENTION

The present invention relates to a non-invasive method of performing annuloplasty. According to one aspect of the present invention, a method for performing annuloplasty includes accessing a left ventricle of a heart to provide a discrete plication element to the left ventricle, and engaging the plication element to tissue near a mitral valve of the heart. Engaging the plication element includes causing the plication element to gather a portion of the tissue to create a plication. In one embodiment, accessing the left ventricle of the heart to provide the plication element includes accessing the left ventricle of the heart using a catheter arrangement.

In another embodiment, engaging the plication element to tissue near the mitral valve includes piercing the tissue using the plication element, which causes a first portion of the plication element to be positioned on an atrial side of the mitral valve and a second portion of the plication element to be positioned on a ventricular side of the mitral valve. In such an embodiment, a delivery catheter may be configured to cause the first portion of the plication element to be positioned on the atrial side of the mitral valve.

Performing an annuloplasty on a mitral valve by accessing the left ventricle of the heart, as for example using a catheter, enables complicated surgical procedures to be avoided when treating mitral valve leakage. Avoiding open-heart surgical procedures generally makes annuloplasty more accessible to patients who may benefit from annuloplasty. As mitral valve leakage is often considered to be an early indicator of congestive heart failure, a minimally invasive annuloplasty procedure that corrects for leakage problems, such as one which involves positioning discrete plications in fibrous tissue around the mitral valve, may greatly improve the quality of life of many patients who might not be suitable for invasive annuloplasty procedures.

According to another aspect of the present invention, a method for performing an annuloplasty includes accessing tissue located near the mitral valve of a heart, and creating a first discrete plication in the tissue using a first plication element. The first discrete plication causes an arc length of the mitral valve to be reduced by effectively shrinking the size of the annulus around the mitral valve. In one embodiment, accessing the tissue includes accessing the tissue through a left ventricle of the heart using a catheter. In such an embodiment, the first plication element may be provided through the catheter.

In other embodiments, the first plication element may be a clip element, a locking element, or an element that includes bar pieces, a thread, and a lock. The thread may generally be a tension element, a flexible tension element, or a suture. Creating the first discrete plication in the tissue using a clip element includes engaging the tissue using the clip element. When the first plication element is a locking element, such as a locking element that includes two pieces, creating the first discrete plication includes penetrating the tissue using a part of the first piece and a part of the second piece, and engaging the tissue between the first piece and the second piece. Alternatively, when the first plication element includes bar pieces, a thread, and a lock, creating the first discrete plication includes penetrating the tissue to position the bar pieces on an atrial side of the tissue, tensioning the thread to position the bar pieces against the atrial side of the tissue, and locking the lock against a ventricular side of the tissue to create the first discrete plication between the bar pieces and the lock.

According to still another aspect of the present invention, a system that is suitable use in an annuloplasty procedure includes a catheter assembly and a bendable member.

The catheter assembly is configured for insertion through an aorta of the heart into a left ventricle of the heart to reach a region of the left ventricle substantially below the mitral valve, and the bendable member is movable between a first position for insertion into a left ventricle through the catheter assembly and a second position. The bendable member is also configured to create a plication in tissue near a mitral valve when it is in the second position.

According to yet another aspect of the present invention, a system that is suitable for use in an annuloplasty procedure includes a catheter assembly and a suture structure. The catheter assembly is configured for insertion through an aorta of the heart into a left ventricle of the heart to reach a region of the left ventricle substantially below the mitral valve. The suture structure includes a first bar member, a second bar member, a thread, and a lock element that moves or slides over the thread. The catheter assembly is further configured to cause the first bar member and the second bar member to penetrate tissue near the mitral valve, and to move the lock element over the thread into contact with the tissue on a ventricular side of the mitral valve. A plication is created in the tissue substantially between the first bar member, the second bar member, and the lock element.

In accordance with another aspect of the present invention, a system for performing annuloplasty on a mitral valve of a heart includes a catheter assembly, a guide element, and a plication element. The catheter assembly is configured for insertion through an aorta of the heart into a left ventricle of the heart to reach a region of the left ventricle substantially below the mitral valve. The guide element is shaped for insertion into the catheter assembly, and the plication element is shaped for insertion over the guide element using the catheter assembly into the left ventricle substantially below the mitral valve. The plication element is configured to gather tissue of the heart to create a plication in the tissue.

These and other advantages of the present invention will become apparent upon reading the following detailed descriptions and studying the various figures of the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention may best be understood by reference to the following description taken in conjunction with the accompanying drawings in which:

5 Fig. 1 is a cross-sectional front-view representation of the left side of a human heart.

Fig. 2a is a cut-away top-view representation of the mitral valve and the aortic valve of Fig. 1.

Fig. 2b is a cut-away representation of a stretched mitral valve and an aortic valve.

10 Fig. 3 is a representation of an annular ring that is suitable for use in performing a conventional annuloplasty procedure.

Fig. 4 is a representation of a mitral valve and an aortic valve after the annular ring of Fig. 3 has been implanted.

15 Fig. 5a is a representation of a mitral valve and an aortic valve after a single edge-to-edge suture has been applied to reduce mitral regurgitation.

Fig. 5b is a representation of a mitral valve and an aortic valve after sutures along a mitral valve annulus have been applied to reduce mitral regurgitation.

Fig. 6a is a representation of a delivery tube and a J-catheter in accordance with an embodiment of the present invention.

20 Fig. 6b is a cut-away front view of the left side of a heart in which the delivery tube and the J-catheter of Fig. 6a have been inserted in accordance with an embodiment of the present invention.

Fig. 7a is a representation of a catheter assembly in accordance with an embodiment of the present invention.

25 Fig. 7b is a cross-sectional representation of the catheter assembly of Fig. 7a in accordance with an embodiment of the present invention.

Fig. 7c is a cut-away top-view representation of a left ventricle in which the gutter catheter of Figs. 7a and 7b has been positioned in accordance with an embodiment of the present invention.

Fig. 8 is a cut-away top-view representation of a left ventricle in which a guide wire has been positioned in accordance with an embodiment of the present invention.

Fig. 9a is a cut-away top-view representation of a left ventricle of the heart in which local plication suture structures have been implanted in accordance with an
5 embodiment of the present invention.

Fig. 9b is a cut-away top-view representation of a left ventricle of the heart in which local plication suture structures which are coupled have been implanted in accordance with an embodiment of the present invention.

Fig. 10a is a representation of a suture structure after T-bars have been introduced
10 to an atrial side of a mitral valve through fibrous tissue near the mitral valve in accordance with an embodiment of the present invention.

Fig. 10b is a representation of the suture structure of Fig. 10a after the T-bars have been engaged to the fibrous tissue in accordance with an embodiment of the present invention.

Fig. 11 is a representation of a suture structure which includes a locking element with a spring in accordance with an embodiment of the present invention.
15

Fig. 12a is a representation of a suture structure which includes a locking element with a resorbable component in accordance with an embodiment of the present invention.

Fig. 12b is a representation of the suture structure of Fig. 12a after the resorbable
20 component has degraded in accordance with an embodiment of the present invention.

Fig. 12c is a representation of the suture structure of Fig. 12b after a plication has been created in accordance with an embodiment of the present invention.

Fig. 13a is a representation of a first catheter which is suitable for use in delivering and implementing a suture structure in accordance with an embodiment of the
25 present invention.

Fig. 13b is a representation of a second catheter which is suitable for use in delivering and implementing a suture structure in accordance with an embodiment of the present invention.

Fig. 13c is a representation of a third catheter assembly which is suitable for use in delivering and implementing a suture structure in accordance with an embodiment of the present invention.

5 Figs. 14a and 14b are a process flow diagram which illustrates the steps associated with one method of performing annuloplasty using a suture structure and a catheter in accordance with an embodiment of the present invention.

Fig. 15 is a cut-away top-view representation of a left ventricle of the heart in which local plication elements have been implanted in accordance with an embodiment of the present invention.

10 Fig. 16a is a representation of a local plication element which has spring-like characteristics in accordance with an embodiment of the present invention.

Fig. 16b is a representation of the local plication element of Fig. 16a after forces have been applied to open the local plication element in accordance with an embodiment of the present invention.

15 Fig. 16c is a representation of the local plication element of Fig. 16b after tips of the local plication element pierce through tissue in accordance with an embodiment of the present invention.

Fig. 16d is a representation of the local plication element of Fig. 16c after the tips of the local plication element engage the tissue to form a local plication in accordance with an embodiment of the present invention.

20 Fig. 17a is a representation of a local plication element, which is formed from a shape memory material, in an open state in accordance with an embodiment of the present invention.

Fig. 17b is a representation of the local plication element of Fig. 17a in a closed state in accordance with an embodiment of the present invention.

Fig. 18a is a representation of a first self-locking clip which is suitable for use in forming a local plication in accordance with an embodiment of the present invention.

Fig. 18b is a representation of a second self-locking clip which is suitable for use in forming a local plication in accordance with an embodiment of the present invention.

Fig. 19 is a representation of a plication-creating locking mechanism in accordance with an embodiment of the present invention.

Fig. 20a is a representation of the plication-creating locking mechanism of Fig. 19 as provided within the left ventricle of a heart in accordance with an embodiment of the present invention.

Fig. 20b is a representation of the plication-creating locking mechanism of Fig. 20a after forces have been applied to cause tines of the mechanism to contact tissue in accordance with an embodiment of the present invention.

Fig. 20c is a representation of the plication-creating locking mechanism of Fig. 20b after tissue has been gathered between the tines of the mechanism in accordance with an embodiment of the present invention.

Fig. 20d is a representation of the plication-creating locking mechanism of Fig. 20c after a local plication has been formed in accordance with an embodiment of the present invention.

Figs. 21a and 21b are a process flow diagram which illustrates the steps associated with one method of performing annuloplasty using a local plication element and a catheter in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF THE EMBODIMENTS

Invasive, open-heart surgical procedures are generally effective in the treatment of mitral valve leakage. However, open-heart surgical procedures may be particularly hazardous to some patients, *e.g.*, frail patients or patients who are considered as being very ill, and undesirable to other patients, *e.g.*, patients who are asymptomatic and do not wish to undergo a surgical procedure. As such, open-heart surgical procedures to correct mitral valve leakage or, more generally, mitral valve insufficiency, are not suitable for many patients who would likely benefit from reducing or eliminating the mitral valve leakage.

A catheter-based annuloplasty procedure enables annuloplasty to be performed on a patient without requiring that the patient undergo open-heart surgery, or be placed on cardiopulmonary bypass. Catheters may be introduced into the left ventricle of a heart

through the aorta to position a guide wire and plication implants on the ventricular side of a mitral valve, *i.e.*, under a mitral valve. Catheters may also be used to couple the plication implants to fibrous tissue associated with the skeleton of the heart around the mitral valve.

5 The use of catheters to perform an annuloplasty procedure by delivering and engaging plication implants or structures enables the annuloplasty procedure to be performed without open-heart surgery, and without a bypass procedure. Recovery time associated with the annuloplasty, as well as the risks associated with annuloplasty, may be substantially minimized when the annuloplasty is catheter-based. As a result,
10 annuloplasty becomes a more accessible procedure, since many patients who might previously not have received treatment for mitral valve leakage, *e.g.*, frail patients and asymptomatic patients, may choose to undergo catheter-based annuloplasty.

 To begin a catheter-based annuloplasty procedure, a delivery tube and a J-catheter may be inserted into a left ventricle of the heart through the aorta. Inserting the delivery
15 tube and the J-catheter through the aorta enables the left ventricle of the heart to be reached substantially without coming into contact with trabeculae or the cordae tendonae in the left ventricle. Fig. 6a is a diagrammatic representation of a delivery tube and a J-catheter in accordance with an embodiment of the present invention. Delivery tube 604 has a substantially circular cross section, and is configured to receive a J-catheter 608. J-
20 catheter 608 is arranged to move longitudinally through an opening in delivery tube 604 as needed.

 In general, delivery tube 604 is an elongated body which may be formed from a flexible, durable, biocompatible material such as nylon, urethane, or a blend of nylon and urethane, *e.g.*, PEBAX®. Likewise, J-catheter 608, which is also an elongated body,
25 may also be formed from a biocompatible material. A material used to form J-catheter 608 is typically also relatively flexible. In the described embodiment, a tip of J-catheter 608 is rigid enough to allow the tip of J-catheter 608 to maintain a relatively curved shape, *e.g.*, a “J” shape. The curve in J-catheter 608 is configured to facilitate the positioning of a gutter catheter, as will be described below with respect to Figs. 7a-c.

Fig. 6b is a schematic representation of delivery tube 604 and J-catheter 608 positioned within a heart in accordance with an embodiment of the present invention. As shown, after delivery tube 604 and J-catheter 608 are effectively "snaked" or inserted through a femoral artery, portions of delivery tube 604 and of J-catheter 608 are positioned within an aorta 620 of a heart 616. A tip 626 of J-catheter 608, which is substantially oriented at a right angle from the body of J-catheter 608, and an end of delivery tube 604 are oriented such that they pass through an aortic valve 630. Hence, an end of delivery tube 604 and tip 626 are positioned at a top portion of left ventricle 624, where wall 632 of left ventricle 624 is relatively smooth. The relative smoothness of the top portion of left ventricle 624 enables a catheter to be properly positioned within left ventricle 624 by guiding the tip of the catheter along wall 632. In one embodiment, tip 626 is oriented such that it is positioned approximately just below a mitral valve 628 on the ventricular side of mitral valve 628.

Once positioned within left ventricle 624, J-catheter 608 may be rotated within delivery tube 604 such that tip 626 is may enable a gutter catheter fed therethrough to run along the contour of wall 632. Typically, the gutter catheter runs along the contour of wall 632 in an area that is effectively defined between a plane associated with papillary muscles 640, a plane associated with the posterior leaflet of mitral valve 628, cordae tendoneae 642, and wall 632. A "gutter" is located in such an area or region and, more specifically, is positioned substantially right under mitral valve 628 where there is a relatively insignificant amount of trabeculae.

With reference to Figs. 7a-7c, a gutter catheter will be described in accordance with an embodiment of the present invention. A gutter catheter 704, which is part of a catheter assembly 702 as shown in Fig. 7a, is arranged to be extended through J-catheter 626 such that gutter catheter 704 may be steered within a left ventricle just beneath a mitral valve. Gutter catheter 704, which may include a balloon tip (not shown), is typically formed from a flexible material such as nylon, urethane, or PEBAX®. In one embodiment, gutter catheter 704, which is steerable, may be formed using a shape memory material.

As shown in Figs. 7a and Fig. 7b, which represents a cross section of catheter assembly 702 taken at a location 710, gutter catheter 704 is at least partially positioned within J-catheter 608 which, in turn, is at least partially positioned within delivery tube 604. Gutter catheter 704 may be free to rotate within and extend through J-catheter 608, while J-catheter 608 may be free to rotate within and extend through delivery tube 604.

Referring next to Fig. 7c, the positioning of gutter catheter 704 within a left ventricle of the heart will be described in accordance with an embodiment of the present invention. It should be appreciated that the representation of gutter catheter 704 within a left ventricle 720 has not been drawn to scale, for ease of illustration and ease of discussion. For instance, the distance between a wall 724 of left ventricle 720 and a mitral valve 728 has been exaggerated. In addition, it should also be appreciated that the positioning of delivery tube 604 and, hence, J-catheter 608 and gutter catheter 704 within aortic valve 732 may vary.

Gutter catheter 704 protrudes through tip 626 of J-catheter 608, and, through steering, essentially forms an arc shape similar to that of mitral valve 728 along the contour of a wall 724 of left ventricle 720 just beneath mitral valve 728, *i.e.*, along the gutter of left ventricle 720. Wall 724 of left ventricle 720 is relatively smooth just beneath mitral valve 728, *i.e.*, generally does not include trabeculae. Hence, inserting catheter assembly 702 through an aortic valve 732 into an upper portion left ventricle 720 allows gutter catheter 704 to be navigated within left ventricle 720 along wall 724 substantially without being obstructed by trabeculae or cordae tendoneae.

Gutter catheter 704 generally includes an opening or lumen (not shown) that is sized to accommodate a guide wire through which a guide wire may be inserted. The opening may be located along the central axis of gutter catheter 704; *i.e.*, central axis 730 as shown in Fig. 7a. Delivering a guide wire through gutter catheter 704 enables the guide wire to effectively follow the contour of wall 724. In general, the guide wire may include an anchoring tip which enables the guide wire to be substantially anchored against wall 724. Fig. 8 is a diagrammatic top-view cut-away representation of a left side of a heart in which a guide wire has been positioned in accordance with an embodiment of the present invention. It should be appreciated that the representation of the left side

of a heart in Fig. 8 has not been drawn to scale, and that various features have been exaggerated for ease of discussion. A guide wire 802 is positioned along wall 724 of left ventricle 720. Once guide wire 802 is inserted through gutter catheter 704 of Figs. 7a-7c, and anchored against wall 724 using an anchoring tip 806, gutter catheter 704, along with J-catheter 708, are withdrawn from the body of the patient. It should be appreciated that delivery tube 604 typically remains positioned within the aorta after guide wire 802 is anchored to wall 724.

Guide wire 802, which may be formed from a material such as stainless steel or a shape memory material, is generally anchored such that guide wire 802 effectively passes along a large portion of wall 724. Typically, guide wire 802 serves as a track over which a catheter that carries plication structures may be positioned, *i.e.*, a lumen of a catheter that delivers a plication element may pass over guide wire 802. Such a catheter may include a balloon structure (not shown), or an expandable structure, that may facilitate the positioning of local plication structures by pushing the local plication structures substantially against the fibrous tissue around the mitral valve.

Forming local plications causes bunches of the fibrous tissue around the mitral valve to be captured or gathered, thereby causing dilation of the anterior leaflet of the mitral valve to be reduced. In general, the local plications are discrete plications formed in the fibrous tissue around the mitral valve using suture structures or discrete mechanical elements. Fig. 9a is a representation of a top-down cut-away view of a left ventricle of the heart in which local plication suture structures have been implanted in accordance with an embodiment of the present invention. Suture structures, which include T-bars 904 and threads 907, are implanted in tissue near a mitral valve 916, *e.g.*, an annulus of mitral valve 916. Typically, the tissue in which suture structures are implanted is fibrous tissue 940 which is located substantially around mitral valve 916. Suitable suture structures include, but are not limited to, structures which include T-bars 904 and threads 907, as will be described below with reference to Figs. 10a, 10b, 11, and 12a-c.

Since T-bars 904 or similar structures, when implanted, may cut through tissue 940, pledgets 905 may against a ventricular side tissue 940 to effectively "cushion" T-bars 904. Hence, portions of T-bars 904 are positioned above mitral valve 916, *i.e.*, on an

atrial side of mitral valve 916, while pledgets 905 are positioned on the ventricular side of mitral valve 916. It should be appreciated that additional or alternative pledgets may be positioned on the atrial side of mitral valve 916, substantially between tissue 940 and T-bars 904. Catheters which deliver suture structures 904 to an atrial side of mitral valve 916 from a ventricular side of mitral valve 916 will be discussed below with respect to Figs. 13a-c.

In the described embodiment, T-bars 904 are coupled such that every two T-bars, *e.g.*, T-bars 904a, is coupled by a thread, *e.g.*, thread 907a. Thread 907a is configured to enable T-bars 904a to be tensioned together and locked against tissue 940. Locking T-bars 904a enables tissue 940 to be bunched or slightly gathered, thereby effectively constraining the size, *e.g.*, arc length, of mitral valve 916 by reducing the an arc length associated with tissue 940. In other words, the presence of T-bars 904 which cooperate with thread 907 to function substantially as sutures, allows the size of a gap 908 between an anterior leaflet 920 and a posterior leaflet 918 to be reduced and, further, to be substantially prevented from increasing. As will be appreciated by those skilled in the art, over time, scar tissue (not shown) may form over pledgets 905 and T-bars 904.

Generally, the number of T-bars 904 used to locally bunch or gather tissue 940 may be widely varied. For instance, when substantially only a small, localized regurgitant jet occurs in mitral valve 916, only a small number of T-bars 904 may be implemented in proximity to the regurgitant jet. Alternatively, when the size of gap 908 is significant, and there is a relatively large amount of mitral valve leakage, then a relatively large number of T-bars 904 and, hence, pledgets 905 may be used to reduce the size of gap 908 by reducing the arc length of mitral valve 916. Some pledgets 905 may be arranged to at least partially overlap. To correct for a regurgitant jet that is centralized to only one section of mitral valve 916, T-bars 904 may be implemented as plicating elements near the regurgitant jet, and as reinforcing elements away from the regurgitant jet, *e.g.*, to prevent progression of mitral valve disease from causing a substantial gap to eventually form.

While the coupling of two T-bars 904a with thread 907a has been described, it should be understood that the number of T-bars 904 coupled by a thread or threads 907

may vary. For example, if multiple T-bars 904 are coupled by multiple threads 907, then it may be possible to gather more fibrous tissue using fewer total T-bars 904. With reference to Fig. 9b, the use of multiple T-bars 904 which are coupled by multiple threads 907 will be described. T-bars 904c are coupled by a thread 907c, while T-bars 904d are coupled by a thread 907c. Similarly, T-bars 904e are coupled by a thread 907e. T-bar 904d' is further coupled by a thread 907f to T-bar 904c'', and T-bars 904d'' is also coupled by a thread 907g to T-bar 904e'. As will be discussed below, threads 907 enable T-bars 904 to be pulled against pledgets 905 and, hence, tissue 940. Such coupling of T-bars 904 enables plications in tissue 940 to be made between T-bars 904c, between T-bars 904d, and between T-bars 904e, while allowing tissue to be at least somewhat gathered between T-bar 904c'' and T-bar 904d', and between T-bar 904d'' and T-bar 904e'.

In general, the configurations of suture structures which include T-bars 904 and threads 907 may vary. One embodiment of a suitable suture structure is shown in Figs. 10a and 10b. Fig. 10a and 10b are representations of a suture structure after T-bars have been introduced to an atrial side of fibrous tissue near a mitral valve in accordance with an embodiment of the present invention. For purposes of illustration, it should be understood that the elements and structures represented in Figs. 10a and 10b, as well as substantially all other figures, have not been drawn to scale. A suture structure 1000 includes T-bars 904, or reinforcing elements, that are coupled to thread 907 such that when thread 907 is pulled, T-bars 904 effectively push against tissue 940. As shown in Fig. 10b, pulling on thread 907 and pushing on a locking element 1002 causes locking element 1002 to contact a ventricular side of tissue 940 and to effectively hold T-bars 904 against tissue 940. Specifically, pulling on a loop 1004 of thread 907 while pushing on locking element 1002 tightens T-bars 904 against tissue 940 such that a plication 1006 may be formed in tissue 940 when locking element 1002 locks into position to lock T-bars 904 into place.

Pledgets 905, as will be appreciated by those skilled in the art, may serve as plication anchors for T-bars 904 which essentially function as sutures. That is, pledgets 905 may prevent T-bars 904 from cutting through tissue 940. In general, the

configuration of pledgets 905 may vary widely. For example, pledgets 905 may have a substantially tubular form, and may be formed from a material such as surgical, *e.g.*, Dacron, mesh. However, it should be appreciated that pledgets 905 may be formed in substantially any shape and from substantially any material which promotes or supports the growth of scar tissue therethrough. Suitable materials include, but are not limited to silk and substantially any biocompatible porous or fibrous material.

Locking element 1002 may be a one-way locking element, *e.g.*, an element which may not be easily unlocked once it is locked, that is formed from a biocompatible polymer. The configuration of a locking element 1002 may be widely varied.

Alternative configurations of locking element 1002 will be described below with respect to Fig. 11 and Figs. 12a-c. In order to engage locking element 1002 against pledgets 905, a catheter which is used to deliver T-bars 904 may be used to push locking element 1002 into a locked position. A catheter which delivers T-bars 904 and may also be used to engage locking element 1002 will be discussed below with reference to Figs. 13a-c.

Like locking element 1002, T-bars 904 may also be formed from a biocompatible polymer. Thread 907, which may be coupled to T-bars 904 through tying T-bars 904 to thread 907 or molding T-bars 904 over thread 907, may be formed from substantially any material which is typically used to form sutures. Suitable materials include, but are not limited to, silk, prolene, braided Dacron, and polytetrafluoroethylene (PTFE, or GoreTex).

As mentioned above, the configuration of locking element 1002 may vary. For example, a locking element may include a spring element as shown in Fig. 11. A suture structure 1100 include T-bars 1104, a thread 1107, and a locking element 1102. For ease of illustration, the elements of suture structure 1100 have not been drawn to scale.

Although suture structure 1100 is not illustrated as including a pledget, it should be appreciated that suture structure 1100 may include a pledget or pledgets which serve as reinforcing elements which generally support the growth of scar tissue.

Locking element 1102 includes solid elements 1102a and a spring element 1102b. Although solid elements 1102a may be formed from a biocompatible polymer, solid elements 1102a may also be formed from material which is typically used to form

pledgets. Spring element 1102b is arranged to be held in an extended position, as shown, while a loop 1114 in thread 1107 is pulled on. Once T-bars 1104 are in contact with tissue 1140, solid elements 1102a may come into contact with tissue 1140, and spring element 1102b may contract to create a spring force that pulls solid elements 1102a toward each other. In other words, once T-bars 1104 are properly positioned against tissue 1140, locking element 1102 may be locked to form a plication or local bunching of tissue 1140.

In one embodiment, the formation of scar tissue on the fibrous tissue which is in proximity to a mitral valve may be promoted before a plication is formed, or before the fibrous tissue is gathered to compensate for mitral valve insufficiency. With reference to Figs. 12a-c, a locking element which promotes the growth of scar tissue before a plication is formed will be described in accordance with an embodiment of the present invention. As shown in Fig. 12a, a suture structure 1200, which is not drawn to scale, includes a locking element 1204, a thread 1207, and T-bars 1204. Locking element 1204, which includes solid elements 1202a, a spring element 1202b, and a resorbable polymer overmold 1202c formed over spring element 1202b is coupled to thread 1207 on a ventricular side of tissue 1240.

Overmold 1202c, which may be formed from a resorbable lactide polymer such as PURASORB, which is available from PURAC America of Lincolnshire, Illinois, is formed over spring element 1202b while spring element 1202b is in an extended position. Overmold 1202c is arranged to remain intact while scar tissue 1250 forms over solid elements 1202a. In one embodiment, in order to facilitate the formation of scar tissue, solid elements 1202a may be formed from material that is porous or fibrous, *e.g.*, “pledget material.”

Once scar tissue is formed over solid elements 1202a, overmold 1202c breaks down, *e.g.*, degrades, to expose spring element 1202b, as shown in Fig. 12b. As will be understood by one of skill in the art, the chemical composition of overmold 1202c may be tuned such that the amount of time that elapses before overmold 1202c breaks down may be controlled, *e.g.*, controlled to break down after a desired amount of scar tissue is expected to be formed. Hence, once overmold 1202c breaks down, and spring element

1202b is allowed to contract, as shown in Fig. 12c, enough scar tissue 1250 will generally have formed over solid elements 1202a to effectively bond solid elements 1202a against tissue 1240 to allow for the formation of a relatively strong plication or gathering of tissue 1240.

5 While a loop 1214 of thread 1207 may be allowed to remain extended into a left ventricle of a heart, thread 1207 may be cut, *i.e.*, loop 1214 may be effectively removed, to reduce the amount of loose thread 1207 in the heart. Alternatively, loose thread 1207 may effectively be eliminated by gathering thread 1207 around a cylindrical arrangement (not shown) positioned over locking element 1202. That is, a spool or similar element
10 may be included as a part of suture structure 1200 to enable loose thread 1207 to either be gathered within the spool or gathered around the exterior of the spool.

 The use of overmold 1202c enables anchoring forces which hold T-bars 1204 and locking element 1202 in position to be relatively low, as substantially no significant forces act on tissue 1240 until after scar tissue or tissue ingrowth is created. Once scar
15 tissue is created, and overmold 1202c has degraded, then spring 1202b compresses. The anchoring forces generated at this time may be relatively high. However, as scar tissue has been created, the likelihood that T-bars 1204 cut into tissue 1240 at this time is generally relatively low.

 As mentioned above, catheters may be used to deliver suture structures into a
20 heart, and to engage the suture structures to tissue around the mitral valve of the heart. One embodiment of a suture structure delivery catheter which is suitable for use in a catheter-based annuloplasty that uses local plications will be described with respect to Fig. 13a. A delivery catheter 1300 may be positioned over a guide wire, *e.g.*, guide wire 802 as shown in Fig. 8, which serves as a track to enable delivery catheter 1300 to be
25 delivered in the gutter of a heart. It should be appreciated that the elements of delivery catheter 1302 have not been drawn to scale. Within delivery catheter 1300 is a wire 1308 which carries T-bars 1304 of a suture structure. In one embodiment, T-bars 1300 are coupled to a thread 1307 and a locking element 1300 to form the suture structure. Typically, a pointed or sharpened end 1311 of wire 1308 is configured to penetrate tissue
30 (not shown), *e.g.*, fibrous tissue of the heart near a mitral valve. Once end 1311 and T-

bar 1304 are located above fibrous tissue, *e.g.*, on an atrial side of a mitral valve, wire 1308 may be retracted and repositioned. After wire 1308 is repositioned, end 1311 may once again penetrate tissue to effectively deposit T-bar 1304 over tissue on the atrial side of the mitral valve.

5 Wire 1308 or, more specifically, end 1311 may be used to pull thread 1307 and to push locking element 1302 into position against tissue near the mitral valve. By way of example, end 1311 may pull on thread 1307 until T-bars 1304 contact the tissue. Then, end 1311 may be used to lock locking element 1302 against the tissue and, as a result, create a plication in the tissue to effectively shrink the annulus of the mitral valve.

10 In order to create additional plications, wire 1308 and, in one embodiment, delivery catheter 1300, may be retracted entirely out of a patient to enable additional T-bars to be loaded onto wire 1308. Once additional T-bars are positioned on wire 1308, wire 1308 may be reinserted into delivery catheter 1300, and delivery catheter 1300 may be used to enable another plication to be created in the tissue which is located near the
15 mitral valve.

Fig. 13b is a representation of a second catheter which is suitable for delivering a suture structure in accordance with an embodiment of the present invention. A catheter 1340, which is not drawn to scale and which may include a lumen (not shown) that is arranged to be inserted over a guide wire, includes two wires 1348 which are arranged to
20 cooperate to carry a suture structure. As shown, wire 1348a carries a T-bar 1344a while wire 1348b carries a T-bar 1344b which are coupled by a thread 1347 and, together with a locking element 1342, form a suture structure. Tips 1351 of wires 1348 pass through tissue near a mitral valve to deposit T-bars 1344 above the mitral valve. Once T-bars 1344 are deposited, tips 1351 may be used to pull T-bars 1344 against the tissue, as well
25 as to lock locking element 1342 against an opposite side of the tissue. By way of example, tip 1351b may be configured to pull on thread 1347 while tip 1351a pushes against locking element 1342.

With reference to Fig. 13c, a catheter arrangement which may deploy T-bars from its tip will be described in accordance with an embodiment of the present invention. A
30 catheter arrangement 1360 includes two catheters which each carry a T-bar 1364. It

should be appreciated that the elements of Fig. 13c have not been drawn to scale for ease of illustration. Specifically, catheter 1360a carries T-bar 1364a at its tip, while catheter 1360b carries T-bar 1364b at its tip. A thread 1367 couples T-bars 1364 together such that a locking element 1362 through which thread 1367 passes may lock T-bars 1364 substantially against tissue of a heart.

In one embodiment, catheter arrangement 1360 may require the use of two guide wires to guide each of catheter 1360a and catheter 1360b into the gutter of the heart. Alternatively, catheter 1360a and catheter 1360b may be arranged such that both catheter 1360a and catheter 1360b may be guided through the gutter of the heart through the use of a single guide wire.

Catheter 1360a is configured to push T-bar 1364a through tissue near the mitral valve of the heart, and to release T-bar 1364a once T-bar 1364a is located on an atrial side of the mitral valve. Similarly, catheter 1360b is configured to push T-bar 1364b through the tissue, and to release T-bar 1364b. T-bars 1364 may be released, for example, when heat is applied to a dielectric associated with catheters 1360 that causes T-bars 1364 to be effectively snapped off. Alternatively, a mechanical mechanism (not shown) that engages T-bars 1364 to catheters 1360 may be disengaged to release T-bars 1364. Once T-bars 1364 are positioned on the atrial side of the mitral valve, catheter 1360 may be used to pull on thread 1367 and to push on locking element 1362.

With reference to Figs. 14a and 14b, the performance of an annuloplasty procedure using a catheter-based system which implants suture structures in tissue near a mitral valve will be described in accordance with an embodiment of the present invention. Once a patient is prepared, *e.g.*, sedated, an annuloplasty procedure 1400 may begin with the insertion of a delivery tube and a J-catheter into the left ventricle of the heart of the patient. The delivery tube and the J-catheter may be inserted into the body of the patient through the femoral artery, and threaded through the femoral artery and the aorta into the left ventricle of the heart. Generally, the J-catheter is positioned within the delivery tube. One embodiment of the delivery tube and a J-catheter were described above with respect to Figs. 6a and 6b. As will be appreciated by those skilled in the art,

the delivery tube and the J-catheter are typically each threaded through the aortic valve to reach the left ventricle.

Once the delivery tube and the J-catheter are positioned within the left ventricle, a gutter catheter may be extended through the J-catheter in step 1408. As was discussed
5 above with reference to Figs. 7a-c, the gutter catheter is arranged to effectively run against a gutter of the wall of the left ventricle substantially immediately under the mitral valve. Specifically, the gutter catheter may be positioned in the space in the left ventricle between the mitral valve and the musculi papillares, or papillary muscles. The gutter catheter often has a tip that is steerable and flexible. In one embodiment, the tip of the
10 gutter catheter may be coupled to an inflatable balloon. The J-catheter serves, among other purposes, the purpose of allowing the gutter catheter to be initially oriented in a proper direction such that the gutter catheter may be positioned along the wall of the left ventricle.

In step 1412, a guide wire with an anchoring feature may be delivered through the
15 gutter catheter, *e.g.*, through a lumen or opening in the gutter catheter. The guide wire is delivered through the gutter catheter such that it follows the contour of the gutter catheter against the wall of the left ventricle. After the guide wire is delivered, the anchoring feature of the guide wire is anchored on the wall of the left ventricle in step 1416. Anchoring the guide wire, or otherwise implanting the guide wire, on the wall of the left
20 ventricle enables the guide wire to maintain its position within the left ventricle.

The J-catheter and the gutter catheter are pulled out of the left ventricle through the femoral artery in step 1420, leaving the guide wire anchored within the left ventricle, as was discussed above with respect to Fig. 8. A T-bar assembly delivery catheter which carries a T-bar assembly is then inserted through the femoral artery into the left ventricle
25 over the guide wire in step 1436. In one embodiment, the T-bar assembly delivery catheter carries an uninflated balloon.

After the T-bar assembly delivery catheter is inserted into the left ventricle, the balloon is inflated in step 1428. Inflating the balloon, *e.g.*, an elastomeric balloon, at a relatively modest pressure using, for example, an air supply coupled to the balloon
30 through the T-bar assembly delivery catheter, serves to enable substantially any catheter

which uses the guide wire as a track to be pressed up against the fibrous tissue around the mitral valve. Generally, the inflated balloon substantially occupies the space between the mitral valve and the papillary muscles. In one embodiment, more than one balloon may be inflated in the left ventricle.

5 Once the balloon is inflated in step 1428. The T-bar assembly delivery catheter effectively delivers T-bars, or similar mechanisms, pledgets, and thread which are arranged to attach or otherwise couple with an annulus of the mitral valve, *e.g.*, the fibrous tissue of the skeleton around the mitral valve, to create plications. Suitable catheters were described above with respect to Figs. 13a-c. In step 1440, a plication is
10 created using the T-bar assembly in substantially any suitable tissue near the mitral valve. For example, a plication may be created by essentially forcing T-bars through the tissue, then locking the T-bars against the tissue using a locking mechanism of the T-bar assembly. Specifically, the plication or bunching of tissue may be created by extending sharpened wires which carry elements such as T-bars through the tissue, then retracting
15 the sharpened wires, and pulling the T-bars into place. Positioning the T-bars, and locking the locking mechanism causes the tissue between the T-bars and the locking mechanism may bunch together.

 Once the plication is created in step 1440, the balloon is generally deflated in step 1442. The T-bar assembly delivery catheter may then be removed through the femoral
20 artery in step 1444. A determination is made in step 1448 after the T-bar assembly delivery catheter is removed as to whether additional plications are to be created. If it is determined that additional plications are to be created, then process flow returns to step 1436 in which the T-bar assembly delivery catheter, which carries a T-bar assembly or suture structure, is reinserted into the femoral artery.

25 Alternatively, if it is determined in step 1448 that there are no more plications to be created, then process flow proceeds to step 1456 in which the guide wire may be removed. After the guide wire is removed, the delivery tube may be removed in step 1460. Once the delivery tube is removed, the annuloplasty procedure is completed.

 In lieu of using suture structures such as T-bar assemblies to create local
30 plications, other elements may also be used to create local plications in fibrous tissue near

the mitral valve during an annuloplasty procedure. Fig. 15 is a cut-away top view representation of a left side of a heart in which local plications have been created using individual, discrete elements in accordance with an embodiment of the present invention. Local plication elements 1522 are effectively implanted in fibrous tissue 1540 around portions of a mitral valve 1516 in order to reduce the size of a gap 1508 between an anterior leaflet 1520 and a posterior leaflet 1518, *e.g.*, to reduce the arc length associated with posterior leaflet 1518. Local plication elements 1522 are arranged to gather sections of tissue 1540 to create local plications. The local plications created by local plication elements 1522, which are generally mechanical elements, reduce the size of the mitral valve annulus and, hence, reduce the size of gap 1508. As will be understood by those skilled in the art, over time, scar tissue may grow around or over local plication elements 1522.

The configuration of local plication elements 1522 may be widely varied. For example, local plication elements 1522 may be metallic elements which have spring-like characteristics, or deformable metallic elements which have shape memory characteristics. Alternatively, each local plication element 1522 may be formed from separate pieces which may be physically locked together to form a plication. With reference to Figs. 16a-d, one embodiment of a local plication element which has spring-like characteristics will be described in accordance with an embodiment of the present invention. A local plication element 1622 may be delivered to a ventricular side, or bottom side, of tissue 1640 which is located near a mitral valve. When delivered, as for example through a catheter, element 1622 is in a substantially folded, closed orientation, as shown in Fig. 16a. In other words, element 1622 is in a closed configuration that facilitates the delivery of element 1622 through a catheter. After an initial compressive force is applied at corners 1607 of element 1622, sides or tines 1609 of element 1622 may unfold or open. As tines 1609 open, tips 1606 of tines 1609 may be pressed against tissue 1640, as shown in Fig. 16b. The application of compressive force to tines 1609, as well as a pushing force to a bottom 1611 of element 1622, allows tips 1606 and, hence, tines 1609 to grab tissue 1640 as tips 1606 push through tissue 1640, as shown in Fig. 16c. The closing of tines 1609, due to compressive forces applied to tines 1609, causes

tissue 1640 to be gathered between tines 1609 and, as a result, causes a plication 1630 to be formed, as shown in Fig. 16d. In one embodiment, the catheter (not shown) that delivers element 1622 may be used to apply forces to element 1622.

As mentioned above, elements used to create local plications may be created from shape memory materials. The use of a shape memory material to create a plication element allows the plication element to be self-locking. Fig. 17a is a representation of one plication element which is formed from a shape memory material in accordance with an embodiment of the present invention. A clip 1704, which may be formed from a shape memory material, *i.e.*, an alloy of nickel and titanium, is arranged to be in an expanded state or open state when it is introduced, *e.g.*, by a catheter, into the gutter of the left ventricle. Typically, holding clip 1704 in an expanded state involves applying force to clip 1704. In one embodiment, a catheter may hold sides 1708 of clip 1704 to maintain clip 1704 in an expanded state.

Once tips 1706 of clip 1704 are pushed through the fibrous tissue near the mitral valve of the heart such that tips 1706 are positioned on an atrial side of the mitral valve, force may be removed from clip 1704. Since clip 1704 is formed from a shape memory material, once force is removed, clip 1704 forms itself into its "rest" state of shape, as shown in Fig. 17b. In its rest state or preferred state, clip 1704 is arranged to gather tissue in an opening 1712 defined by clip 1704. That is, the default state of clip 1704 is a closed configuration which is effective to bunch tissue to create a local plication.

Another discrete self-locking plication element which is suitable for creating a local plication is a clip which may twist from an open position to a closed, or engaged position, once force applied to hold the clip in an open position is removed. Fig. 18a is a representation of another self-locking plication element shown in a closed position in accordance with an embodiment of the present invention. A clip element 1800, which may be formed from a material such as stainless steel or a shape memory material, is preloaded such that once tissue 1830 is positioned in a gap 1810 between a tine 1806 and a time 1808, clip element 1800 may return to a state which causes tissue 1830 to be pinched within a gap or space 1810.

Tine 1806 and tine 1808 first pierce tissue 1830, *e.g.*, the tissue of an annulus of a mitral valve. As tine 1806 and tine 1808 are drawn together to create a plication, thereby reducing the size of gap 1810 by reducing a distance 1820, a bottom portion 1812 of clip element 1800 twists, as for example in a quarter turn, effectively by virtue of shape memory characteristics of clip element 1800. Thus, an effective lock that holds tine 1806 and tine 1808 in a closed position such that tissue 1830 is gathered to form a local plication results.

In lieu of a preloaded clip element, a clip element may include a lock mechanism which engages when force is applied. Fig. 18a is a representation of a self-locking plication element which includes a sliding lock in accordance with an embodiment of the present invention. A clip element 1850 includes a body 1852 and a slider 1862 which is arranged to slide over at least a portion of body 1852. Clip element 1850, which may be formed from a material such as stainless steel or a shape memory alloy, includes a tip 1856 and a tip 1858 which are substantially separated by a gap 1856 when slider 1862 is in an unlocked position. As shown, slider 1862 is in an unlocked or open position when slider 1862 is positioned about a tapered neck 1854 of body 1852.

When clip element 1850 is delivered into a left ventricle, *e.g.*, using a catheter, clip element 1850 is positioned within the left ventricle such that tip 1856 and tip 1858 are effectively pierced through fibrous tissue 1880 near the mitral valve. After tip 1856 and tip 1858 are positioned substantially on an atrial side of tissue 1880, force may be applied to slider 1862 to move slider 1862 in a y-direction 1870b over body 1852. As slider moves in y-direction 1870b away from tapered neck 1854, slider 1862 forces tip 1856 and tip 1858 together close gap 1860, *i.e.*, tip 1856 and tip 1858 move towards each other in an x-direction 1870a. When tip 1856 and tip 1858 cooperate to close gap 1860, tissue 1880 is gathered within clip element 1850, thereby creating a local plication.

In one embodiment, when slider 1862 is in a closed position such that tip 1856 and tip 1858 cooperate to close gap 1856, slider 1862 may contact tissue 1880. Hence, in order to promote the growth of scar tissue over parts of clip element 1850 or, more specifically, slider 1862, at least a top surface of slider 1862 may be covered with a pledget material, *e.g.*, a mesh which supports the growth of scar tissue therethrough.

Locking elements which create local plications may include elements which have two or more substantially separate pieces which lock together around tissue. An example of a locking element which includes two separate pieces is shown in Fig. 19. As shown in Fig. 19, a locking element 2000 may include a receiver piece 2002 and a locker piece 2004, which may generally be formed from substantially any suitable material, as for example a biocompatible plastic material. Receiver piece 2002 and locker piece 2004 each include a tine 2006. Tines 2006 are arranged to pierce and to engage tissue to create a local plication.

A cable tie portion 2010 of locker piece 2004 is configured to be drawn through an opening 2008 which engages cable tie portion 2010. Opening 2008 includes features (not shown) which allow cable tie portion 2010 to be pulled through opening 2008 and locked into position, and which prevent cable tie portion 2010 substantially from being pushed out of opening 2008. Cable tie portion 2010 is locked in opening 2008 when bevels 2012 come into contact and effectively force tines 2006 to clamp down. Once tines 2006 clamp down, and locker piece 2004 is locked against receiver piece 2002, a local plication is formed.

The operation of locking element 2000 will be described with respect to Figs. 20a-d in accordance with an embodiment of the present invention. As shown in Fig. 20a, receiver piece 2002 and locker piece 2004 may be delivered substantially beneath fibrous tissue 2050 near a mitral valve (not shown). Receiver piece 2002 and locker piece 2004 may be delivered using a catheter which includes a top surface 2054. Top surface 2054 of the catheter is arranged to apply force to tines 2006 such that tines 2006 remain in an effectively undeployed, *e.g.*, partially bent or folded, position while being delivered by the catheter.

Once receiver piece 2002 and locker piece 2004 are positioned under tissue 2050 near a location where a plication is to be formed, forces are applied to receiver piece 2002 and locker piece 2004 to push receiver piece 2002 and locker piece 2004 together and effectively through an opening 2058 in top surface 2054 of the catheter, as shown in Fig. 20b. The forces are typically applied by mechanisms (not shown) associated with

the catheter. As tines 2006 pass through opening 2058, tines 2006 "open," or deploy in order to pierce tissue 2050.

After piercing tissue 2050, tines 2006 continue to penetrate and to gather tissue 2050 while receiver piece 2002 and locker piece 2004 are pushed together. As receiver
5 piece 2002 and locker piece 2004 are pushed together, cable tie portion 2010 is inserted into opening 2008 (shown in Fig. 19) of receiver portion 2002, as shown in Fig. 20c. Cable tie portion 2010 eventually locks with respect to opening 2008 when bevels 2012 come into contact. When bevels 2012 come into contact, tines 2006 close inwards, causing tissue 2050 to be captured, *i.e.*, causing a local plication 2060 to be formed.

10 Once a local plication is formed, and force is no longer required to push receiver piece 2002 and locker piece 2004 together, the catheter which delivered receiver piece 2002 and locker piece 2004 may be removed from the left ventricle.

Referring next to Figs. 21a and 21b, an annuloplasty procedure which uses a
15 catheter-based system to create local plications in tissue near a mitral valve using discrete elements will be described in accordance with an embodiment of the present invention. After a patient is prepared, an annuloplasty procedure 2100 may begin with the insertion of a delivery tube and a J-catheter into the left ventricle of the heart of the patient in step 2104. Once the delivery tube and the J-catheter are positioned within the left ventricle, a gutter catheter may be extended through the J-catheter in step 2108. The gutter catheter,
20 as described above, is arranged to effectively run against a gutter of the wall of the left ventricle, *e.g.*, between the mitral valve and the papillary muscles. The gutter catheter often has a tip that is steerable and flexible.

In step 2112, a guide wire with an anchoring feature may be delivered through the gutter catheter, *e.g.*, through a lumen or opening in the gutter catheter. The guide wire is
25 delivered through the gutter catheter such that it follows the contour of the gutter catheter against the wall of the left ventricle. After the guide wire is delivered, the anchoring feature of the guide wire is anchored on the wall of the left ventricle in step 2116.

The J-catheter and the gutter catheter are pulled out of the left ventricle through the femoral artery in step 2120, leaving the guide wire anchored within the left ventricle,
30 as was discussed above with respect to Fig. 8. A plication element delivery catheter

which carries a plication element and, in one embodiment, is arranged to engage the plication element to the fibrous tissue around the mitral valve is inserted through the femoral artery into the left ventricle over the guide wire in step 2132. The plication element delivery catheter, in the described embodiment, is coupled to an uninflated
5 balloon which is inflated in step 2134 to effectively allow the plication element delivery catheter to be positioned substantially directly under the fibrous tissue. Once the plication element delivery catheter is positioned in the left ventricle, *e.g.*, over the guide wire in the gutter of the left ventricle, and the balloon is inflated, the plication element delivered by the delivery catheter is engaged to the fibrous tissue in step 2136. That is,
10 the plication element is coupled to the fibrous tissue such that a local plication is formed in the fibrous tissue.

After the local plication is created in step 2136 by engaging tissue using the plication element, the balloon is deflated in step 2138. Upon deflating the balloon, the plication element delivery catheter may be removed through the femoral artery in step
15 2140. A determination is then made in step 2142 as to whether additional local plications are to be created. That is, it is determined if other plication elements are to be introduced into the left ventricle. If it is determined that additional local plications are to be created, process flow returns to step 2132 in which the plication element delivery catheter, which carries another plication element, is reinserted into the femoral artery.

20 Alternatively, if it is determined in step 2142 that there are no more local plications to be created, then the indication is that a sufficient number of local plications have already been created. Accordingly, the guide wire may be removed in step 2148, and the delivery tube may be removed in step 2152. After the delivery tube is removed, the annuloplasty procedure is completed.

25 Although only a few embodiments of the present invention have been described, it should be understood that the present invention may be embodied in many other specific forms without departing from the spirit or the scope of the present invention. By way of example, methods of introducing plication elements or suture structures into the left ventricle to correct for mitral valve leakage, or mitral valve insufficiency, may be
30 applied to introducing plication elements or suture structures which correct for leakage in

other valves. For instance, the above-described procedure may be adapted for use in repair a leaking valve associated with a right ventricle.

While creating local plications in fibrous tissue associated with the mitral valve of the heart has generally been described, the plications may also be created in other types of tissue which are near, around, in proximity to, or include the mitral valve. Other tissues to which an plications may be formed include tissues associated with the myocardium, or tissues associated with the wall of the left ventricle. In one embodiment, a plication may be substantially directly formed in the leaflets of the mitral valve.

It should be understood that although a guide wire has been described as including an anchoring tip to anchor the guide wire to a wall of the left ventricle, a guide wire may be anchored with respect to the left ventricle in substantially any suitable manner. By way of example, a guide wire may include an anchoring feature which is located away from the tip of the guide wire. In addition, a guide wire may more generally be any suitable guiding element which is configured to facilitate the positioning of an implant.

While access to the gutter of the left ventricle has been described as being associated with a minimally invasive catheter annuloplasty procedure in which local plications are formed, it should be understood that the gutter of the left ventricle may also be accessed, e.g., for an annuloplasty procedure, as a part of a surgical procedure in which local plications are formed. For instance, the aorta of a heart may be accessed through an open chest surgical procedure before a catheter is inserted into the aorta to reach the left ventricle. Alternatively, suture structures or plications elements may be introduced on a ventricular side of a mitral valve through a ventricular wall which is accessed during an open chest surgical procedure.

Pledgets have been described as being used in conjunction with, or as a part of, suture structures to facilitate the growth of scar tissue as a result of an annuloplasty procedure. It should be appreciated, however, that the use of pledgets is optional. In addition, although pledgets have generally not been described as being used with clip elements which create local plications, it should be understood that pledgets may also be implemented with respect to clip elements. By way of example, a clip element which

includes tines may be configured such that the tines pierce through pledgets before engaging tissue without departing from the spirit or the scope of the present invention.

When a clip element has tines that are arranged to pierce through a pledget before engaging tissue, the pledget may be of a hollow, substantially cylindrical shape that enables the pledget be delivered to a left ventricle over a guide wire positioned in the gutter of the left ventricle. The clip element may then be delivered by a catheter through the pledget. A substantially cylindrically shaped, hollow pledget which is to be used with a suture structure may also be delivered over a guide wire, and the suture structure may then be delivered through the pledget. Delivering the suture structure through the pledget may enable a loop of thread that remains after the suture structure is locked into place to remain substantially within the pledget.

The configuration of clip elements may generally vary widely. Specifically, the shape of clip elements, the size of clip elements, and the materials from which the clip elements are formed may be widely varied. For instance, in addition to clip elements that are formed from shape memory material, preloaded, or self-locking using mechanical structures, clip elements may also be formed from thermally expandable materials. That is, a clip may be formed such that it is in an open or flat position when delivered into a left ventricle. Such a clip may have an outer or "bottom" element that has a relatively high coefficient of thermal expansion, and an inner or "top" element that deforms under the load generated by the outer element when heat is applied to cause the outer element to bend. Such a clip, once bent or deformed through the application of heat, may pierce tissue. When more heat is applied, the clip may bend more such that tissue is engaged between ends or sides of the clip to create a local plication. In such a system, the inner material may be arranged to maintain its deformed shape once heat is no longer applied, and the heat may be applied through a catheter.

Suture structures and plication elements have been described as being used to correct for mitral valve insufficiency. In general, suture structures and plication elements may also be used to essentially prevent the onset of mitral valve insufficiency. That is, local plications may be created to effectively stem the progression of mitral valve insufficiency by reinforcing the perimeter of the annulus around the mitral valve.

While suture structures that include T-bars, thread, and locking elements, and are delivered to a left ventricle using a catheter, may be used to form discrete plications in fibrous tissue around the mitral valve, it should be appreciated that sutures may also be sewn into the fibrous tissue. For example, a catheter which is inserted into the left
5 ventricle through the aorta may be configured to sew sutures into the fibrous tissue using mechanisms carried by the catheter. Such sutures that are sewn into the fibrous tissue may be sewn in any conventional orientation, *e.g.*, in an arc along the perimeter of the posterior leaflet of the mitral valve.

Suture structures that include T-bars have generally been described as including
10 two T-bars which are located at ends of a thread, with a locking element and pledgets located therebetween, as shown, for example, in Fig. 10a. The configuration of suture structures, however, may vary widely. By way of example, a suture structure with two T-bars may include one T-bar at one end of the thread and a second T-bar which is located along the length of the thread such that pulling on a loose end of the thread pulls the two
15 T-bars together. Alternatively, a suture structure may include more than two T-bars.

In general, the use of a single element type to create local plications during an annuloplasty procedure has been described. It should be understood that in one embodiment, different element types may be used in a single annuloplasty procedure. For instance, both clip elements and suture elements may be used to create plications
20 during a single annuloplasty procedure. Alternatively, different types of clip elements or different types of suture elements may be used during a particular annuloplasty procedure.

The steps associated with performing a catheter-based annuloplasty may be widely varied. Steps may generally be added, removed, reordered, and altered without
25 departing from the spirit or the scope of the present invention. Therefore, the present examples are to be considered as illustrative and not restrictive, and the invention is not to be limited to the details given herein, but may be modified within the scope of the appended claims.